

**REMARKS**

Reconsideration of the above identified application in view of this Amendment is respectfully requested. This Amendment is in response to the Office Action dated April 17, 2006. By said Office Action, claims 1 - 15 were rejected under 35 U.S.C. §102(b) as being anticipated by Andreiko et al. (U.S. Patent No. 5,368,478).

Summary of the Applicant's amendments of the claims is as follows:

Independent system claim 1 and dependent claims 3, 4, 5, 6, and 7, therefrom, have been amended. Claim 2 remains in original form.

Independent method claim 8 (corresponding to independent system claim 1) and dependent claims 10, and 11, therefrom, have been amended. Claim 9 remains in original form.

Independent device claim 12, and dependent claims 13, 14, and 15, therefrom, remain in original form.

The claims were amended by strictly relying upon the specification of the originally disclosed invention, without adding new subject matter. Words, phrases, and terms used for amending the claims are directly and literally obtained from, and supported by, the specification of the originally disclosed invention, and are not obtained from, or supported by, hints, suggestions, and/or creative deductions, drawn from the specification of the originally disclosed invention. Moreover, independent claims 1 and 8, reading upon the system and method, respectively, of the present invention, were amended to be totally consistent with, and complementary to, each other. Dependent claims 3, 4, 5, 6, and 7, and, claims 10 and 11, therefrom, respectively, were similarly amended.

The Examiner is respectfully made aware that the US Patent Application Publication, to Anisimov et al., having US Patent Publication Application No. US 2004/0143186 A1, published on July 22, 2004, of the present U.S. Patent Application No. 10/681,906, was used for preparing the present Amendment. Accordingly, Applicant's references to page and paragraph numbers correspond to those of the just stated publication document of the present patent application.

Briefly, the present invention relates to systems and methods for ultrasonic imaging of a jaw and coupling cushions suited for use in the mouth of a patient. The system includes a specially configured (curved wand type) ultrasonic probe, upon which is mounted a (correspondingly curved) array of transducers, a position locator module for defining a probe location and transmitting the definition to a central processing unit (CPU)

and the CPU. The CPU is capable of receiving digital data from the curved array of transducers in the probe and receiving the location of the probe and producing an image of at least a portion of a jaw. The method includes providing the ultrasonic probe, defining its location and communicating the location to a CPU and transmitting a signal from a transducer and receiving at least a portion of the signal at least one of the transducers. The CPU receives transducer data and a location of the probe and produces an image of the at least a portion of the jaw of the patient. Also disclosed is an ultrasonic coupling cushion, structured and functional for engaging and retaining at least a portion of the (curved wand type) ultrasonic probe.

### **35 U.S.C. §102(b) Rejections**

The Examiner rejected claims 1 - 15 under 35 U.S.C. §102(b) as being anticipated by Andreiko et al. (U.S. Patent No. 5,368,478).

The Examiner's rejection is respectfully traversed, particularly regarding the subject matter pertaining to the structure and function (operation) of the ultrasonic probe, as recited in original claims 3, 4, 10, 11; pertaining to the structure and function (operation) of the position locator module, as recited in original claims 5 and 6; and pertaining to the structure and function (operation) of the ultrasonic coupling cushion, as recited in original claims 12 - 15.

The invention illustratively described in the Andreiko, et al. patent relates to a "Method for forming jigs for custom placement of orthodontic appliances on teeth". Moreover, therein, in the Abstract, it is stated: "Orthodontic appliance placement jigs are provided (for) positioning and orienting the appliance at connection points on the teeth of a patient, particularly for positioning brackets against the surfaces of the teeth so that they can be bonded thereto. The jigs are formed with numerical controlled machinery that develops jig forming instructions from digitized tooth shape data and from digital representations of the tooth finish positions and appliance design. The jig forming instructions are preferably derived from the same data and digital information from which the tooth finish positions and custom appliance geometry are calculated".

In the Andreiko, et al. disclosure, in the Summary of the Invention section, col. 4, lines 39 - 45, it is stated:

"In accordance with the preferred and illustrated embodiment of the invention, the digitized information is generated from measurements from the mouth of the patient, either

taken directly or from a model thereof, and preferably includes information of the shapes of the individual teeth of the patient and of the patient's lower jaw".

Additionally, in the Andreiko, et al. disclosure, in the Summary of the Invention section, col. 5, lines 27 - 45, it is stated:

"In certain embodiments of the invention, images are digitized to produce the tooth and jaw shape data. Preferably, the images include a scanner which, in one form, generates a video image from which selected points are digitized to produce data from which finish tooth positioning and appliance design is carried out. Alternatively, three dimensional imaging of the teeth and jaw of the patient is carried out with laser or other scanner to form full three dimensional images of the teeth and jaw of the patient. The images may be formed from the patient's teeth and jaw or from a model thereof. Additional data is digitized by taking vertical profiles of the patient's teeth, either by tracing with a computer the three dimensional images generated with other scanners, or by scanning with a mechanical contact probe or with a non-contact probe the individual teeth of the patient, or model thereof. The data may be taken directly from the patient using CAT scans, MRI, positron emission tomography or other technique".

Additionally, in the Andreiko, et al. disclosure, in the Detailed Description of the Drawings section, col. 11, lines 53 - 63, it is stated:

"In accordance with alternative embodiments of the invention, digitization of anatomical information for computer input is performed either at the appliance design and manufacturing facility, by the orthodontist at his office, or preferably divided between the two. Similarly, the present invention contemplates the manufacture of the appliance to be performed at either the appliance manufacturing facility, at the orthodontists office, or preferably divided between the two locations and in accordance with the analysis and design provided by the system of the present invention".

Additionally, in the Andreiko, et al. disclosure, in the Detailed Description of the Drawings section, col. 13, lines 2 - 55, it is stated:

"Referring to the system diagram of FIG. 1, an orthodontic appliance manufacturing and patient treatment system 10 is illustrated. The system components are distributed between two locations, a doctor's office 11, and an appliance design and manufacturing facility 13. At the doctor's office 11, a patient 12, who requires orthodontic treatment, is examined by an orthodontist 14, who makes a diagnosis 15 of the condition of the patient and of the treatment, if any, needed. The examination involves the traditional application of the skill, knowledge and expertise of the orthodontist 14, and results in the

preparation of detailed records 16 of the anatomy and condition of the mouth 18 of the patient, of the treatment proposed, and of other information necessary to the preparation of an orthodontic appliance.

The records 16 prepared by the orthodontist include a **physical model 20 from a mold of the patient's mouth 18**, which includes a mandibular model 21 of the patient's lower jaw or mandible 22 and a maxillary model 23 of the patient's upper jaw or maxilla 24. The records 16 also include prescription 27 wherein the orthodontist sets forth a treatment to be applied to the patient and a result to be achieved by the treatment. The prescription 27 may also include a specification of techniques that are to be included in the treatment and a designation of an orthodontic appliance to be employed. The records 16 will further include identification information 17 and patient history information 19.

In the illustrated embodiment of the invention, the records 16 are transmitted to the appliance manufacturing facility 13, at which the finish position of the teeth are calculated and a custom appliance 25 is designed and manufactured. The facility 13 is provided with one or more trained operators 28. In some embodiments, the physical model 20 itself is transmitted in the information 16 to the facility 13. In such cases, one of the primary functions of the operators 28 is to input digital information 26 from the records 16 into a computer 30a. Another function is to operate the same or another computer 30b to design the custom appliance 25, and to operate NC equipment 38 controlled by one of the same or another computer 30c to manufacture the appliance 25. Where the inputting, design and manufacture are performed at the appliance facility 13, the computers 30a, 30b and 30c may be the same computer 30.

In other embodiments of the invention, the orthodontist 14 digitizes data from the model 20, in which case the inputting computer 30 is located at the orthodontist's office 11. In these embodiments, the digitized information 26, rather than the physical model 20, is transmitted to the appliance facility 13. The analyzing and appliance design computer is nonetheless preferably at the appliance facility 13".

Based on the preceding, in the Andreiko, et al. disclosure, although it is literally stated that "the digitized information is generated from measurements from the mouth of the patient, either taken directly or from a model thereof, and that "The images may be formed from the patient's teeth and jaw or from a model thereof", it is also literally stated that "The records 16 prepared by the orthodontist include a physical model 20 from a mold of the patient's mouth 18", and that ". . . the orthodontist 14 digitizes data from the model 20", and that "The analyzing and appliance design computer is nonetheless

**preferably at the appliance facility 13**". Moreover, the entire Andreiko, et al. disclosure is clearly focused on, and limited to, illustratively describing implementation of the invention by imaging of **a model** of a patient's mouth, and **not** by imaging a patient's mouth itself. Thus, it is clear to one of ordinary skill in the art that the intended (preferred) implementation of the invention described by Andreiko, et al., is clearly focused on, and limited to, imaging of **a model** of a patient's mouth, and **not** imaging of a patient's mouth itself, and therefore does not anticipate the present invention.

By strong contrast, the present invention relates to systems and methods for ultrasonic imaging of a jaw and coupling cushions especially suited for **use in the mouth of a patient**. Moreover, the improved ultrasonic imaging system is constructed, and operated, to facilitate imaging of at least a portion of a jaw, where the jaw may be either the upper jaw (maxilla) or the lower jaw (mandible) of a subject, as illustratively described, and claimed, in the present application. As explained in detail hereinbelow, the present invention includes several novel and inventive aspects which are clearly not anticipated (i.e., are different and distinguishable) from, or obviously derived from, the invention disclosed by Andreiko, et al., wherein such patentable aspects are used for amending the claims of the present invention.

In the Applicant's disclosure of the present invention, in the Detailed Description of the Preferred Embodiments section, page 7, paragraphs [0101] - [0102], along with reference to FIGS. 21, 22a, and 22b, there is stated:

"According some preferred embodiments of system 520, probe 522 is a mandibular probe designed and constructed to facilitate imaging of at least a portion of a lower jaw 521. The mandibular probe 522 (see figure 21) includes a first array 524 of ultrasonic transducers mounted upon a first **wand** 530. First array 524 of ultrasonic transducers is positionable distal to lower jaw 521 and outside of a mouth 529. Mandibular probe 522 further includes a second array 526 of ultrasonic transducers mounted upon a second **wand** 532. **Second array 526 of ultrasonic transducers is positionable proximal to lower jaw 521 and inside of mouth 529.** Mandibular probe 522 further includes at least one connective member 528 (534). The connective member is designed and constructed to connect the first and second wands 530 and 532 one to another and to allow relative positioning thereof. The connective member 528 includes an assembly designed and constructed to attach the first and second wands and facilitate translational motion (534) of the wands with respect to one another. In the pictured embodiment, complementary

arcuate teeth 533 and gears 531 are employed to facilitate translational motion (534) of the wands 530 and 532 with respect to one another although any known mechanical, electrical or robotic means might be employed without significantly altering the invention. In the pictured embodiment cable 535 is employed for data transfer to CPU 536 although transfer via microwave, RF or infrared may alleviate the requirement for a physical connection between components of system 520.

According to alternate preferred embodiments of the invention, probe 522 (shown in greater detail in figures 22a and b) is designed and constructed to facilitate imaging of at least a portion of an upper jaw (maxilla; 523) and includes a single **curved array 524 of ultrasonic transducers mounted upon a wand 530 which is designed and constructed to be insertable into a mouth 529 of a patient**. Transducers 524 are preferably mounted on an inner surface of curved wand 530 which can transverse, or straddle, maxilla 523 at a chosen point".

Based on the preceding illustrative description of the system, in general, and of the probe, in particular, of the present invention, the Applicant has amended independent system claim 1, by including more limiting recitation of the structure / function of the probe. Specifically, wherein amended claim 1 includes recitation of the probe as follows:

- (a) a probe comprising at least one curved wand whereupon each is mounted a curved array of ultrasonic transducers, wherein at least one said curved wand is designed and constructed to be insertable into a mouth of a patient;

The remaining recitation of original claim 1 has been amended in order to be consistent with the antecedent basis established by the initial recitation of 'a curved array' in the recitation of the 'probe' in amended claim 1.

The Applicant strongly contends that recitation of the structure / function of the probe, and therefore, recitation of the structure / function of the system, in amended independent system claim 1, are not anticipated or obviously derived from the disclosure of Andreiko, et al..

In the Andreiko, et al. disclosure, in the Detailed Description of the Drawings section, from col. 13, line 56, to col. 14, line 3, there is stated:

"The entry of the information into the input computer 30 involves a digitizing of the information 16 to produce the digitized anatomical information 26 in machine readable form for analysis by the analyzing computer 30b. The input computer 30 connected thereto by a scanner 33, which, in the alternative embodiments of the invention, includes equipment that employs one or more video cameras, mechanical probes, laser scanners,

ultrasonic scanners, moire image scanners or other forms of imaging or measurement hardware that alone, or in combination with other such components, produce anatomical geometric information that describes the patient's teeth and jaw. The images may be three-dimensional or be made along a plurality of planes or other surfaces that can ultimately be combined to provide information in three dimensions".

In the Andreiko, et al. disclosure, illustrative details of the scanner 33 are provided in the Description of the Drawings section, from col. 15, line 40, to col. 18, line 68, along with the figures referenced therein. Therein, particular attention is directed to the "Mechanical Probe Digital Scanner Assembly 57", illustratively described from col. 17, line 61, to col. 18, line 68, along with reference to FIGS. 1A, 1B, and 1C, and especially, with reference to FIG. 1C.

Therein, from col. 17, line 62, to col. 18, line 41, it is stated:

"The scanner may also include, alternatively or in combination with other scanning equipment such as the video scanner assembly 43 of FIG. 1A or the laser scanning assembly of FIG. 1B above, a mechanical probe assembly 57 as illustrated in FIG. 1C. This entire assembly 57 is used in the illustrated embodiment of the invention in combination with the video scanner 43 to derive labial-lingual vertical profiles of the individual teeth of the patient from the model 20 to supplement jaw and horizontal tooth dimensional and shape information derived from a video image produced by the video scanner 43 from the model 20. Alternatively, portions of this assembly can be used to produce the same information from a three dimensional image 55 produced by equipment such as the laser scanning assembly 50.

Referring to FIG. 1C, the probe assembly 57 includes a measurement probe 60 which is moveable over the individual teeth of the model 21 to produce an electrical signal that is digitized for computer input of point locations or profiles of the surfaces of the teeth in separate X-Y for each tooth. In the illustrated embodiment of the process of the invention, the information 26 preferably derived from the model 21 includes the tooth profiles curves  $PF_1$  in a labial-lingual plane viewed in a mesial-to-distal direction.

The probe assembly 57 further includes a magnetic base 59 upon which is mounted the model 20, and from which extends an upstanding vertical support 58 on which the probe 60 is mounted. The probe tip 60a is freely rotatable about a vertical axis on which its tip lies, while the probe itself is hooked to allow the tip to track recesses in the surfaces of the teeth of the model 21. The probe 60 is mounted on the support 58 to move in X and Y directions in a vertical plane preferably that extends through the support

58 and the probe 60. In this manner, the probe tip 60a is positioned to scan the surface of a tooth of the model 21 along this plane. The probe 60 is linked to the support 58 through a pair of orthogonal measurement position transducers 61, which respectively generate electrical analog measurements of the positions of the tip of the probe 60 along respective ones of the X-Y orthogonal coordinates. The outputs of the transducers 61 are connected to circuitry that generates a Sequence of periodic readings of the transducer measurements of the probe tip positions which are then digitized. These outputs are sent in along lines 61a connected to input computer 30, preferably to a serial port thereof".

Based on the preceding detailed discussion comparing, and contrasting, the structure / function (operation) of the Applicant's system, in general, and probe, in particular, to the structure / function (operation) of the Andreiko, et al. system, in general, and probe, in particular, the Applicant strongly contends that the preceding description of the "Mechanical Probe Digital Scanner Assembly 57", included in the Andreiko, et al. disclosure, clearly, and unambiguously, does not anticipate, nor is it obvious to one of ordinary skill in the art to derive, the structure / function of the probe included in the imaging system of the present invention, as recited in amended independent system claim 1, namely,

"a probe comprising at least one curved wand whereupon each is mounted a curved array of ultrasonic transducers, wherein at least one said curved wand is designed and constructed to be insertable into a mouth of a patient".

Accordingly, the Applicant believes that the amendment of independent system claim 1 completely overcomes the Examiner's rejection to claim 1 based on grounds of 35 U.S.C. §102(b), and therefore, amended independent claim 1 is in allowable form, and such action is respectfully requested.

By this Amendment, recitation of dependent claim 2 remains in original form.

By this Amendment, recitations of dependent claims 3, 4, 5, 6, and 7, depending from independent claim 1, were amended in order to be consistent with the recitation of amended independent claim 1.

Accordingly, since original dependent claim 2, and amended dependent claims 3, 4, 5, 6, and 7, depend from an allowable base claim, i.e., amended independent claim 1, therefore, original dependent claim 2, and amended dependent claims 3, 4, 5, 6, and 7, are also in allowable form, and such action is respectfully requested.



In view of the above discussion regarding Applicant's overcoming Examiner's rejection to claim 1 based on grounds of 35 U.S.C. §102(b), by this Amendment, the Applicant has amended independent method claim 8 in a manner 'identically' corresponding to amendment of original independent system claim 1.

Specifically, the Applicant has amended independent method claim 8, by including more limiting recitation of the structure / function of the probe which is provided by step (a). More specifically, wherein amended claim 8 includes recitation of the probe provided by step (a) as follows:

- (a) providing a probe comprising at least one curved wand whereupon each is mounted a curved array of ultrasonic transducers, wherein at least one said curved wand is designed and constructed to be insertable into a mouth of a patient;

The Applicant strongly contends that the preceding description of the "Mechanical Probe Digital Scanner Assembly 57", as included in the Andreiko, et al. disclosure, clearly, and unambiguously, does not anticipate, nor is it obvious to one of ordinary skill in the art to derive, the structure / function of the probe which is provided by step (a) of the imaging method of the present invention, as recited in amended independent method claim 8.

Accordingly, the Applicant believes that the amendment of independent method claim 8 completely overcomes the Examiner's rejection to claim 8 based on grounds of 35 U.S.C. §102(b), and therefore, amended independent claim 8 is in allowable form, and such action is respectfully requested.

By this Amendment, recitation of dependent claim 9 remains in original form.

By this Amendment, recitations of dependent claims 10, and 11, depending from independent claim 8, were amended in order to be consistent with the recitation of amended independent claim 8.

Accordingly, since original dependent claim 9, and amended dependent claims 10, and 11, depend from an allowable base claim, i.e., amended independent claim 8, therefore, original dependent claim 9, and amended dependent claims 10, and 11, are also in allowable form, and such action is respectfully requested.

The Applicant strongly contends that the subject matter pertaining to the structure and function (operation) of the ultrasonic coupling cushion, as recited in original claims 12 - 15, of the present invention, is clearly not inherently met by the Andreiko, et al. disclosure, and is clearly not anticipated by, nor obviously derived from, the Andreiko, et

al. disclosure. More specifically, nowhere throughout the entire disclosure of the Andreiko, et al. patent is there any explicit (direct) or implicit (indirect or suggestive) literal description or figurative illustration of the 'ultrasonic coupling cushion' (or equivalent thereof) which is recited in claims 12 - 15, and illustratively described (in particular, on page 8, paragraphs [0105], [0107], and [0108], along with reference to FIGS. 25 and 22b), in the specification of the present invention.

In the Applicant's disclosure of the present invention, in the Detailed Description of the Preferred Embodiments section, page 8, paragraph [0105], along with reference to FIG. 25, there is stated:

"Preferably system 520 further includes an ultrasonic coupling cushion 550 (see figure 25). Cushion 550 includes an elastic container 552 capable of retaining a coupling medium 554 therein. **Elastic container 552 is designed and constructed to be insertable in a mouth of a subject** and will typically have a thickness of 2 to 20 mm. Cushion 550 is positioned between probe 522 and jaw 521 or 523. **Cushion 550 obviates the need for conductive fluid or gel inside the mouth so that an image may be acquired without requiring the patient to spit or rinse. Further, cushion 550 may be used between probe 522 the face in the case of a mandibular probe which has one array of transducers 524 located outside mouth 529. This eliminates the need to apply conductive gel to the face which may be especially important to patients with beards.** Additional details of the configuration of cushion 550 are provided hereinbelow".

In view of the immediately preceding statements, and in view of the hereinabove discussion wherein the Applicant has shown and stated that ". . . the entire Andreiko, et al. disclosure is clearly focused on, and limited to, illustratively describing implementation of the invention by imaging of **a model** of a patient's mouth, and **not** by imaging a patient's mouth itself. Thus, it is clear to one of ordinary skill in the art that the intended (preferred) implementation of the invention described by Andreiko, et al., is clearly focused on, and limited to, imaging of **a model** of a patient's mouth, and **not** imaging of a patient's mouth itself, and therefore does not anticipate the present invention", including the subject matter pertaining to the structure and function (operation) of the ultrasonic coupling cushion, as recited in original claims 12 - 15, and illustratively described in the specification of the present invention.

Additionally, the Applicant strongly contends that one of ordinary skill in the art of the invention would have had absolutely no motivation for even considering using the 'ultrasonic coupling cushion' (or equivalent thereof) which is recited in claims 12 - 15, for

implementing the invention disclosed by Andreiko, et al., singly, or in combination with another technique.

Accordingly, the Applicant firmly believes that independent claim 12, and claims 13, 14, and 15, depending therefrom, are allowable in their original forms.

The Applicant believes the preceding remarks completely overcome the Examiner's rejection to original claims 12 - 15 based on grounds of 35 U.S.C. §102(b), and therefore, original claims 12 - 15 are in allowable form, and such action is respectfully requested.

In view of the discussion above in the context of the 35 U.S.C. §102(b) rejections, the Applicant submits that amended independent claim 1, original dependent claim 2, and amended dependent claims 3, 4, 5, 6, and 7; amended independent claim 8, original dependent claim 9, and amended dependent claims 10 and 11; and, original independent claim 12, and original dependent claims 13, 14, and 15, are allowable, and such action is respectfully requested.

In view of the foregoing, by this Amendment, it is submitted that all the claims now pending in the application are allowable over the cited prior art. An early Notice of Allowance is therefore respectfully requested.

Respectfully submitted,



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**Encl:**

Petition for Two-Month Extension Fee